

100



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/535,005	03/23/2000	William S. Bess	PD A0000259-03EJF	1060

7590 12/13/2004  
 Burton A. Amernick  
 Connolly Bove Lodge & Hutz LLP  
 1990 M Street NW  
 Washington, DC 20036

EXAMINER

PESELEV, ELLI

ART UNIT	PAPER NUMBER
----------	--------------

1623

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/535,005

Applicant(s)

BESS ET AL.

Examiner

Elli Peselev

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 14-19, 21, 22, 25-29 and 33-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 14-19, 21, 22, 25-29 and 33-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

Art Unit: 1623

Claims 1-4, 14-19, 21, 22, 25-29 and 33-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichman (U.S. Patent No. 5,980,882) in combination with Schiraldi et al (U.S. Patent No. 4,713,243) for the reasons set forth in the Office Action of September 21, 2004.

Applicant's arguments filed November 29, 2004 have been considered but have not been found persuasive.

Applicant contends that Eichman fails to suggest an orally-consumable solid film. Said argument has not been found persuasive because such films were known in the art at the time the instant invention was made as disclosed by Schiraldi et al. Applicant also contends that Schiraldi et al fails to suggest that films therein could be used in conjunction with a complex of a pharmaceutically active agent and an ion exchange resin and that the structures of Schiraldi are intended to adhere to and remain in place over extended period of time which is in contrast to the fast dissolving films of the present invention. This argument has not been found persuasive. Schiraldi et al disclose a film containing a pharmaceutical agent which can adhere to a wet mucuous surface. Eichman disclose a pharmaceutical agent comprising a complex of pharmaceutical agent with an ion exchange resin. To use a pharmaceutical agent disclosed by Eichman in the film disclosed by Schiraldi et al would have been prima facie obvious to a person having ordinary skill in the art at the time the instant invention was made. Further, note that present claims fail to state how fast the film dissolves in the mouth. Also, no evidence has been presented showing that the claimed film has a

Art Unit: 1623

thickness or moisture content which is different from the thickness or moisture content of the film disclosed by Schiraldi et al.

Therefore, the claimed film is still deemed prima facie obvious over the cited prior art.

Claims 1-4, 14-19, 21, 22, 28, 29 and 33-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,596,298 in view of Eichman (U.S. Patent No. 5,980,882). For the reasons set forth in the Office Action of September 21, 2004.

Applicant's arguments filed November 29, 2004 have been considered but have not been found persuasive.

Since the terminal disclaimer has not been filed at the time of the present office Action, the above rejection has not been overcome.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

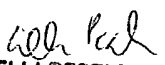
Art Unit: 1623

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

  
ELLI PESELEV  
PRIMARY EXAMINER  
GROUP 1200